# IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE HEMISPHERX BIOPHARMA, INC. LITIGATION

CIVIL ACTION NO. 09-CV-5262

# ANSWER AND DEFENSES OF DEFENDANTS TO CONSOLIDATED [AMENDED] CLASS ACTION COMPLAINT

Defendants Hemispherx Biopharma, Inc. ("Hemispherx" or "the Company"), William A. Carter, M.D., and David R. Strayer, M.D. (collectively "defendants"), by their attorneys, hereby answer the allegations of the Consolidated [Amended] Class Action Complaint ("Complaint") as follows:

# **ANSWER AND FIRST DEFENSE**

- 1. Deny each and every averment of paragraph 1 of the Complaint; except admit that Lead Plaintiff purports to bring this action under the referenced statutory provisions and Securities and Exchange Commission ("SEC") rule on behalf of all persons or entities that purchased or acquired Hemispherx common stock between February 18, 2009 and December 1, 2009 ("putative Class Period").
- 2. Deny each and every averment of paragraph 2 of the Complaint; except are without knowledge or information sufficient to form a belief as to the truth of the averments regarding Lead Plaintiff's alleged personal knowledge and the investigation allegedly conducted by Lead Plaintiff and its attorneys, and said averments are therefore deemed denied.
- 3. Deny each and every averment of paragraph 3 of the Complaint; except admit that Hemispherx's corporate offices are located in Philadelphia, Pennsylvania, that Hemispherx is engaged in the development of immune based drug therapies, including

Ampligen® for the treatment of Chronic Fatigue Syndrome ("CFS"), that Hemispherx received approval from the U.S. Food and Drug Administration ("FDA" or "the Agency") to sell Alferon N Injection® for the treatment of refractory genital warts, that commercial sales of Alferon N Injection® were halted in 2008, and that Hemispherx is developing Alferon LDO® (low dose oral); and further aver that, to the extent that the allegations of paragraph 3 purport to paraphrase documents that describe Hemispherx's business, the contents of such writings speak for themselves.

- 4. Deny each and every averment of paragraph 4 of the Complaint; except admit that Hemispherx filed its initial Ampligen® New Drug Application ("NDA") with the FDA in 2007.
- 5. Deny each and every averment of paragraph 5 of the Complaint; except admit that Hemispherx publicly reported each occasion on which the FDA advised the Company that the Agency's review of the Ampligen® NDA would be delayed; and further aver that Hemispherx's press releases, SEC filings, and other written or transcribed public statements regarding the Company's communications with the FDA are publicly available writings, the contents of which speak for themselves.
- 6. Deny each and every averment of paragraph 6 of the Complaint; and further aver that, to the extent these averments purport to characterize statements made in Hemispherx's SEC filings, the contents of such writings speak for themselves.
- 7. Deny each and every averment of paragraph 7 of the Complaint; except admit that Hemispherx requested that the FDA waive certain requirements for carcinogenicity studies; and further aver that the FDA's requirements and guidelines for the purpose, use, and standards for the design and analysis of clinical and other studies are set forth in the Agency's

regulations, industry guidance documents and other written guidelines, and that these government documents, as well as Hemispherx's press releases, SEC filings, and other written or transcribed public statements regarding the Company's communications with the FDA, are publicly available writings, the contents of which speak for themselves.

- 8. Deny each and every averment of paragraph 8 of the Complaint; except admit that, after the FDA accepted Hemispherx's NDA for Ampligen® as sufficiently complete for substantive review, that the Agency requested certain additional information®, and that Hemispherx responded to the FDA's requests; and further aver that these requests are referenced in Hemispherx's press releases, SEC filings, and/or other written or transcribed public statements, which are publicly available writings, the contents of which speak for themselves.
- 9. Deny each and every averment of paragraph 9 of the Complaint; except admit that, on February 18, 2009 and May 26, 2009, Hemispherx issued press releases reporting that the FDA had advised the Company that the Agency's review of the Ampligen<sup>®</sup> NDA would be delayed; and further aver that the February 18, 2009 and May 26, 2009 press releases, as well as Hemispherx's SEC filings and any other written or transcribed public statements that refer to these communications from the FDA, are publicly available writings, the contents of which speak for themselves.
- 10. Deny each and every averment of paragraph 10 of the Complaint; except admit that, on March 19, 2009, Dr. Strayer participated in an investor conference call; and further aver that the March 19, 2009 conference call was transcribed and that the transcript is a publicly available writing, the contents of which speak for themselves.
- 11. Deny each and every averment of paragraph 11 of the Complaint; except admit that paragraph 11 contains a partial excerpt, with emphasis supplied by Lead Plaintiff,

from a press release issued by Hemispherx on November 2, 2009; and further aver that the November 2, 2009 press release is a publicly available writing, the contents of which speak for themselves.

- 12. The averments of paragraph 12 of the Complaint purport to state a legal conclusion to which no response is required, and therefore are deemed denied. To the extent these averments are deemed to be factual in nature, they are denied; except that defendants admit that Hemispherx's common stock closed at \$1.45 per share on October 30, 2009, at \$1.33 per share on November 2, 2009, and at \$1.13 per share on November 3, 2009.
- 13. Deny each and every averment of paragraph 13 of the Complaint; except admit that paragraph 13 contains partial excerpts, with emphasis supplied by Lead Plaintiff, from a press release issued by Hemispherx on December 1, 2009, reporting the status of the Ampligen<sup>®</sup> NDA; and further aver that this press release is a publicly available writing, the contents of which speak for themselves.
- 14. The averments of paragraph 14 of the Complaint purport to state a legal conclusion to which no response is required, and therefore are deemed denied. To the extent these averments are deemed to be factual in nature, they are denied, except that defendants admit that Hemispherx's common stock closed at \$1.20 per share on December 1, 2009, at \$0.71 per share on December 2, 2009, and at \$0.68 per share on December 3, 2009.
  - 15. Admit the averments of paragraph 15 of the Complaint.
  - 16. Deny each and every averment of paragraph 16 of the Complaint.
- 17. Deny each and every averment of paragraph 17 of the Complaint; except admit that Hemispherx's corporate offices are located in this district and that venue lies in this district.

- 18. Deny each and every averment of paragraph 18 of the Complaint; except admit that Hemispherx uses the United States mail, interstate telephone communications, and the facilities of a national securities exchange.
- 19. Deny each and every averment of paragraph 19 of the Complaint; and further aver that the Certifications referenced in this paragraph are writings the contents of which speak for themselves.
  - 20. Admit the averments of paragraph 20 of the Complaint.
- 21. Deny each and every averment of the fourth sentence of paragraph 21 of the Complaint, except admit that Dr. Carter reviewed, approved, and signed certain of Hemispherx's SEC filings during the putative Class Period; and further admit the averments of the first three sentences of this paragraph.
- 22. Deny each and every averment of the second sentence of paragraph 22 of the Complaint; and admit the averments of the first sentence of this paragraph.
- 23. Deny each and every averment of paragraph 23 of the Complaint; except admit that the requirements for FDA approval of prescription drugs for marketing and sale are set forth in the Federal Food, Drug, and Cosmetic Act and in FDA regulations, industry guidance documents and other written guidelines, and that these government documents are publicly available writings, the contents of which speak for themselves; and further aver that the FDA's requirements and guidelines for approval are further defined and explained by the Agency in its direct correspondence, discussions and other communications with new drug sponsors.
- 24. Deny each and every averment of paragraph 24 of the Complaint; except admit that Hemispherx is seeking FDA approval of Ampligen<sup>®</sup> for the treatment of CFS and that the FDA's requirements for obtaining approval of a particular prescription drug and for labeling

and marketing the drug once it is approved are set forth in FDA regulations, industry guidance documents and other written guidelines, which are publicly available writings, the contents of which speak for themselves, and are further defined and explained by the FDA in its direct correspondence, discussions and other communications with new drug sponsors.

- 25. Deny each and every averment of paragraph 25 of the Complaint; except admit that the FDA's requirements and guidelines for the purpose, design, conduct, analysis, and results of clinical trials, including the Agency's guidance for interpreting clinical trial data, are set forth in FDA regulations, industry guidance documents and other written guidelines, which are publicly available writings, the contents of which speak for themselves, and are further defined and explained by the FDA in its direct correspondence, discussions and other communications with new drug sponsors.
- 26. The averments of paragraph 26 of the Complaint purport to state a legal conclusion to which no response is required, and therefore are deemed denied. To the extent these averments are deemed to be factual in nature, they are denied; except that defendants admit that the requirements and guidelines for the purpose, use, and collection of "user fees" by the FDA are set forth in the Prescription Drug User ree Act, as amended, as well as the Agency's implementing regulations, industry guidance documents and other written guidelines, which are publicly available writings the contents of which speak for themselves.
- 27. The averments of paragraph 27 of the Complaint purport to state a legal conclusion to which no response is required, and therefore are deemed denied. To the extent these averments are deemed to be factual in nature, they are denied; except that defendants admit that the federal statutory requirements and guidance documents setting forth the purpose, use,

and commencement of the "PDUFA clock" are publicly available writings, the contents of which speak for themselves.

- 28. Admit the averments of paragraph 28 of the Complaint.
- 29. Deny each and every averment of paragraph 29 of the Complaint; except admit that in the 1970s, Dr. Carter co-invented Ampligen<sup>®</sup>.
- 30. Deny each and every averment of paragraph 30 of the Complaint; except admit that Hemispherx has sought FDA marketing approval for Ampligen<sup>®</sup> as a treatment for CFS, and that Hemispherx continues to explore Ampligen<sup>®</sup>'s possible use as a treatment for other medical conditions.
- 31. Deny each and every averment of paragraph 31 of the Complaint; except admit that DuPont entered into and exited a collaboration with Hemispherx's predecessor, HEM Research, Inc., and acquired approximately 6% of HEM Research's stock, that Ampligen® has not been approved for the treatment of AIDS, and that Dr. Carter left his position as Hemispherx's CEO in 1988; and are without knowledge or information sufficient to form a belief as to the truth of the averments regarding DuPont's reasons for purchasing Hemispherx stock and subsequently terminating its collaboration with the Company.
- 32. Deny each and every averment of paragraph 32 of the Complaint; except admit that the alleged criteria referenced in this paragraph are set forth on the website of the U.S. Centers for Disease Control & Prevention ("CDC"), which is a writing, the contents of which speak for themselves.
- 33. Deny each and every averment of paragraph 33 of the Complaint; except admit that CFS patients experience a wide range of symptoms; are without knowledge or information sufficient to form a belief as to the truth of the averments regarding any alleged

symptoms reported by unnamed CFS patients and said averments are therefore deemed denied; and further aver that, to the extent this paragraph purports to excerpt, paraphrase or characterize information obtained from the CDC website, the contents of such writing speak for themselves.

- 34. Deny each and every averment of paragraph 34 of the Complaint; except admit that Dr. Carter has served as an officer of Hemispherx, including its predecessor companies HEM Research, Inc. and HEM Pharmaceuticals Corp., since 1989, that, in 1991, the Company sought FDA approval to provide Ampligen® to patients with CFS under a treatment Investigational New Drug Application ("IND"), and that, in 1992, the Agency approved the Company's IND and authorized the Company to begin a Phase II study of Ampligen® for the treatment of CFS; further aver that FDA treatment IND requirements are set forth in the Agency's regulations, industry guidance documents, and other written guidelines, which are writings the contents of which speak for themselves; and incorporate by reference defendants' response to paragraph 35 of the Complaint as though fully set forth herein.
- 35. Deny each and every averment of paragraph 35 of the Complaint; except admit that the FDA sent Hemispherx a letter in October 1991 regarding the Company's treatment IND for Ampligen®, which letter is a writing, the contents of which speak for themselves, and further admit that, in October 1992, the FDA authorized Hemispherx to begin a Phase II study of Ampligen® for the treatment of CFS.
- 36. Deny each and every averment of paragraph 36, except admit that the results of the Phase II study of Ampligen<sup>®</sup> were published in 1994 in the University of Chicago peer-reviewed journal *Clinical Infectious Diseases* under the title, "A controlled clinical trial with a specifically configured RNA drug, Poly(I):Poly(C12U), in Chronic Fatigue Syndrome,"

which, as a writing, the contents speak for themselves and are incorporated by reference as though fully set forth herein.

- 37. Deny each and every averment of paragraph 37 of the Complaint; except admit that in 1998, the FDA authorized Hemispherx to begin enrolling patients for the Ampligen<sup>®</sup> Phase III trial, that the protocol for the Ampligen<sup>®</sup> Phase III trial included the same dosage regimen as did the protocol for the Phase II trial but extended the treatment to 40 weeks, and that paragraph 37 contains a partial excerpt, with emphasis supplied by plaintiffs, from a press release issued by Hemispherx on May 3, 2006, discussing the results from the Ampligen<sup>®</sup> Phase III trial; and further aver that the press release is a writing, the contents of which speak for themselves.
- 38. Admit the averments of the first four sentences of paragraph 38 of the Complaint, and aver that the FDA's Refusal to File letter is a writing, the contents speak for themselves; denies the averments of the fifth sentence of paragraph 38, and avers that the Company has publicly stated that its NDA for Ampligen<sup>®</sup> is the first NDA ever accepted for review by the FDA for systemic use of a toll-like receptor (TLR) therapy to treat any condition.
- 39. Deny each and every averment of paragraph 39 of the Complaint; except admit that the original PDUFA date was February 25, 2009, and that on December 1, 2009, Hemispherx issued a press release reporting that the Company had received a Complete Response Letter from the FDA; and further aver that the December 1, 2009 press release is a writing, the contents of which speak for themselves.
- 40. Deny each and every averment of paragraph 40 of the Complaint; except admit that Hemispherx received FDA approval to sell Alferon N Injection<sup>®</sup> for the treatment of refractory genital warts; and further aver that the Company's 2008 Form 10-K, filed with the

SEC on March 16, 2009, which public document Lead Plaintiff alleges as a source for certain of its averments in paragraph 40, is a writing, the contents of which speak for themselves; and expressly deny Lead Plaintiff's mischaracterizations and false representations of the contents of this writing.

- 41. Deny each and every averment of paragraph 41 of the Complaint; except admit that Hemispherx had an accumulated debt of approximately \$206 million as of September 30, 2009, and that paragraph 41 contains a partial excerpt from Hemispherx's 2009 Form 10-Q for the quarter ended March 31, 2009, filed with the SEC on May 11, 2009; and further aver that said SEC filing is a writing, the contents of which speak for themselves.
- 42. Deny each and every averment of paragraph 42 of the Complaint; except admit that paragraph 42 contains a partial excerpt, with emphasis supplied by plaintiffs, from Hemispherx's 2008 Form 10-K, filed with the SEC on March 16, 2009; and further aver that said SEC filing is a writing, the contents of which speak for themselves.
- 43. Deny each and every averment of paragraph 43 of the Complaint; except admit that paragraph 43 contains a partial excerpt, with emphasis supplied by Lead Plaintiff, from Hemispherx's Form 10-Q for the quarter ended September 30, 2009, filed with the SEC on November 9, 2009; and further aver that said SEC filing is a writing, the contents of which speak for themselves.
- 44. Deny each and every averment of paragraph 44 of the Complaint; except admit the averments in subparagraphs a, b, c, and d thereof.
- 45. Deny each and every averment of paragraph 45 of the Complaint; except admit that this paragraph contains a partial excerpt from an investor conference call hosted by Hemispherx on March 19, 2009; and further aver that the March 19, 2009 conference call was

transcribed and that the transcript is a publicly available writing, the contents of which speak for themselves.

- 46. Deny each and every averment of paragraph 46 of the Complaint; except admit that this paragraph contains a partial excerpt from an investor conference call hosted by Hemispherx on March 19, 2009; and further aver that the March 19, 2009 conference call was transcribed and that the transcript is a publicly available writing, the contents of which speak for themselves.
- 47. Deny each and every averment of paragraph 47 of the Complaint; except admit that this paragraph contains a partial excerpt, with emphasis supplied by plaintiffs, from a press release issued by Hemispherx on February 18, 2009, reporting that the Company had received a letter from the FDA advising that the PDUFA date for the Ampligen® NDA would be extended by three months; and further aver that said press release is a writing, the contents of which speak for themselves.
- 48. Deny each and every averment of paragraph 48 of the Complaint; except admit that this paragraph contains a partial excerpt from Hemispherx's Form 10-Q for the quarter ended September 30, 2009, filed with the SEC on November 9, 2009; and further aver that said SEC filing is a writing, the contents of which speak for themselves.
- 49. Deny each and every averment of paragraph 49 of the Complaint; except admit that this paragraph contains a partial excerpt, with ellipses and emphasis supplied by Lead Plaintiff, from Hemispherx's 2008 Form 10-K, filed with the SEC on March 16, 2009; further aver that said SEC filing is a writing the contents of which speak for themselves; and expressly deny Lead Plaintiff's mischaracterizations and false representations of the contents of this writing.

- 50. Deny each and every averment of paragraph 50 of the Complaint; and further avert that Hemispherx's 2008 Form 10-K, referenced in this paragraph, is a publicly available writing, the contents of which speak for themselves..
- 51. Deny each and every averment of paragraph 51 of the Complaint; except admit that paragraph 51 contains a partial excerpt from an abstract of Dr. Strayer's presentation at the 9th International IACFS/ME Research and Clinical Conference held on March 12-15, 2009, which abstract is posted on the IACFS/ME website and is a writing, the contents of which speak for themselves; and expressly deny Lead Plaintiff's mischaracterizations and false representations of the contents of this writing.
- 52. Deny each and every averment of paragraph 52 of the Complaint; except admit that this paragraph contains a partial excerpt, with emphasis supplied by Lead Plaintiff, from an investor conference call hosted by Hemispherx on March 19, 2009, discussing the status of the Ampligen<sup>®</sup> NDA; and further aver that the March 19, 2009 conference call was transcribed and that the transcript is a publicly available writing, the contents of which speak for themselves.
- 53. Deny each and every averment of paragraph 53 of the Complaint; and further aver that the transcript of the March 19, 2009 conference call and the November 2, 2009 press release, referenced in this paragraph, are publicly available writings, the contents of which speak for themselves.
- 54. Deny each and every averment of paragraph 54 of the Complaint; except admit that this paragraph contains a partial excerpt, with ellipses supplied by Lead Plaintiff, from an investor conference call hosted by Hemispherx on March 19, 2009; further aver that the March 19, 2009 conference call was transcribed and that the transcript is a publicly available

writing, the contents of which speak for themselves; and expressly deny Lead Plaintiff's mischaracterizations and false representations of the contents of this writing.

- 55. Deny each and every averment of paragraph 55 of the Complaint; except admit that paragraph 55 contains a partial excerpt, with ellipses supplied by Lead Plaintiff, from an investor conference call hosted by Hemispherx on March 19, 2009, and further aver that the March 19, 2009 conference call was transcribed and that the transcript is a publicly available writing, the contents of which speak for themselves.
- 56. Deny each and every averment of paragraph 56 of the Complaint; except admit that paragraph 56 purports to summarize and contains a partial excerpt from an investor conference call hosted by Hemispherx on March 19, 2009; and further aver that the March 19, 2009 conference call was transcribed and that the transcript is a publicly available writing, the contents of which speak for themselves.
- admit that paragraph 57 contains a partial excerpt from a press release issued by Hemispherx on December 1, 2009, discussing the status of the Ampligen® NDA; further aver that the December 1, 2009 press release and the FDA guidance document also referenced in paragraph 57 are publicly available writings, the contents of which speak for themselves; expressly deny Lead Plaintiff's mischaracterizations and false representations of these writings; and incorporate by reference defendants' responses to paragraphs 52-56 of the Complaint as though fully set forth herein.
- 58. Deny each and every averment of paragraph 58 of the Complaint; except admit that this paragraph contains a partial excerpt from a press release issued by Hemispherx on

December 1, 2009; and further aver that the press release is a writing, the contents of which speak for themselves.

- 59. Deny each and every averment of paragraph 59 of the Complaint; except admit that this paragraph contains a partial excerpt, with emphasis supplied by Lead Plaintiff, from an investor conference call hosted by Hemispherx on March 19, 2009; and further aver that the March 19, 2009 conference call was transcribed and that the transcript is a publicly available writing, the contents of which speak for themselves.
- 60. Deny each and every averment of paragraph 60 of the Complaint; further aver that the December 1, 2009 press release is a writing, the contents of which speak for themselves; expressly deny Lead Plaintiff's mischaracterizations and false representations of the contents of this writing; and incorporate by reference defendants' response to paragraph 59 of the Complaint as though fell set forth herein.
- 61. Deny each and every averment of paragraph 61 of the Complaint; except admit that this paragraph contains a partial excerpt from a press release issued by Hemispherx on May 11, 2009, entitled "Hemispherx Biopharma Announces \$18.3 Million Public Equity Offerings"; and further aver that the press release is a writing, the contents of which speak for themselves.
- 62. Deny each and every averment of paragraph 62 of the Complaint; except admit that this paragraph contains a partial excerpt from Hemispherx's Form 10-Q for the quarter ended March 31, 2009, filed with the SEC on May 11, 2009; and further aver that said SEC filing is a writing, the contents of which speak for themselves.
- 63. Deny each and every averment of paragraph 63 of the Complaint; except admit that this paragraph contains a partial excerpt from a press release issued by Hemispherx on

May 19, 2009; and further aver that the press release is a writing, the contents of which speak for themselves.

- 64. Admit the averments of paragraph 64.
- 65. Deny each and every averment of paragraph 65 of the Complaint; except admit that this paragraph contains a partial excerpt, with emphasis supplied by Lead Plaintiff, from a press release issued by Hemispherx on May 26; and further aver that the press release is a writing, the contents of which speak for themselves.
- 66. Deny each and every averment of paragraph 66 of the Complaint; except admit that this paragraph contains a partial excerpt from an interview *biomedreports.com* conducted with Dr. Carter on June 12, 2009; and further aver that the June 12, 2009 interview was transcribed and that the transcript is a publicly available writing, the contents of which speak for themselves.
- 67. Deny each and every averment of paragraph 67 of the Complaint; further aver that the November 2, 2009 press release is a writing, the contents of which speak for themselves; expressly deny Lead Plaintiff's mischaracterizations and false representations of the contents of this writing; and incorporate by reference defendants' response to paragraph 66 of the Complaint as though fully set forth herein.
- 68. Deny each and every averment of paragraph 68 of the Complaint; except admit that this paragraph contains a partial excerpt, with ellipses and emphasis supplied by Lead Plaintiff, from an investor conference call hosted by Hemispherx on July 22, 2009; and further aver that the July 22, 2009 conference call was transcribed and that the transcript is a publicly available writing, the contents of which speak for themselves.

- 69. Deny each and every averment of paragraph 69 of the Complaint; except admit that this paragraph contains a partial excerpt, with ellipses supplied by Lead Plaintiff, from an SEC Form 10-Q filed by Hemispherx on August 10, 2009; and further aver that said SEC filing is a writing, the contents of which speak for themselves.
- 70. Deny each and every averment of paragraph 70 of the Complaint; except admit that this paragraph contains a partial excerpt, with ellipses and emphasis supplied by Lead Plaintiff, from an article published on September 19, 2009, on *TheStreet.com*; further aver that said article is a writing, the contents of which speak for themselves; and expressly deny the false statements and misrepresentations contained in that article.
- 71. Deny each and every averment of paragraph 71 of the Complaint; except admit that this paragraph contains a partial excerpt from an interview *biomedreports.com* conducted with Dr. Carter on October 9, 2009, discussing the status of the Ampligen<sup>®</sup> NDA; and further aver that the October 9, 2009 interview was transcribed and that the transcript is a publicly available writing, the contents of which speak for themselves.
- 72. Deny each and every averment of paragraph 72 of the Complaint; and incorporate by reference defendants' responses to paragraphs 47-71 of the Complaint as though fully set forth herein.
- 73. Deny each and every averment of paragraph 73 of the Complaint; except admit that this paragraph contains a partial excerpt from a press release issued by Hemispherx on November 2, 2009, entitled "Hemispherx Biopharma Updates Chronic Fatigue Syndrome (CFS) Treatment and Commercial Application Programs; Targets Completion of All NDA Regulatory Responses and Initiation of Expanded Clinical Collaborations in CFS"; further aver that the

press release is a writing, the contents of which speak for themselves; and expressly deny Lead Plaintiff's mischaracterizations and false representations of the contents of this writing.

- 74. The averments of paragraph 74 of the Complaint purport to state a legal conclusion to which no response is required, and therefore are deemed denied. To the extent these averments are deemed to be factual in nature, they are denied; except that defendants admit that Hemispherx common stock closed at \$1.45 per share on October 30, 2009, and at \$1.33 per share on November 2, 2009, and at \$1.13 per share on November 3, 2009.
- 75. Deny each and every averment of paragraph 75 of the Complaint; except admit that this paragraph contains a partial excerpt, with emphasis supplied by Lead Plaintiff, from an article published on November 3, 2009, on *TheStreet.com*; further aver that said article is a writing, the contents of which speak for themselves; and expressly deny the false statements and misrepresentations contained in that article.
- 76. Deny each and every averment of paragraph 76 of the Complaint; except admit that a purported class action lawsuit was filed against Hemispherx in November 2009, that the Company believes, and has publicly stated, that the claims asserted therein are without merit; and that paragraph 76 purports to paraphrase and contains partial excerpts from a press release issued by Hemispherx on November 16, 2009; further aver that the November 16, 2009 press release is a writing, the contents of which speak for themselves; and expressly deny Lead Plaintiff's mischaracterizations and false representations of the contents of this writing.
- 77. Deny each and every averment of paragraph 77 of the Complaint; except admit that this paragraph purports to summarize and contains a partial excerpt, with emphasis supplied by Lead Plaintiff, from a press release issued by Hemispherx on December 1, 2009 regarding the FDA's Complete Response Letter; further aver that the press release is a writing,

the contents of which speak for themselves; and expressly deny Lead Plaintiff's mischaracterizations and false representations of the contents of this writing.

- 78. The averments of paragraph 78 of the Complaint purport to state a legal conclusion to which no response is required, and therefore are deemed denied. To the extent these averments are deemed to be factual in nature, they are denied; except that defendants admit that Hemispherx's common stock closed at \$1.20 per share on December 1, 2009, at \$0.71 per share on December 2, 2009, and at \$0.68 per share on December 3, 2009.
- 79. The averments of paragraph 79 of the Complaint purport to state a legal conclusion to which no response is required, and therefore are deemed denied. To the extent these averments are deemed to be factual in nature, they are denied. Defendants also incorporate by reference their responses to paragraphs 77-78 of the Complaint as though fully set forth herein.
- 80. Deny each and every averment of paragraph 80 of the Complaint; except admit that paragraph 80 contains a partial excerpt, with ellipsis and emphasis supplied by Lead Plaintiff, from an article published on December 2, 2009 on *TheStreet.com*; further aver that said article is a writing, the contents of which speak for themselves; and expressly deny the false statements and misrepresentations contained in that article.
  - 81. Deny each and every averment of paragraph 81 of the Complaint.
  - 82. Deny each and every averment of paragraph 82 of the Complaint.
- 83. Deny each and every averment of paragraph 83 of the Complaint; except admit that Dr. Carter entered a Standby Financing Agreement with Hemispherx in February 2009; and further aver that the Standby Financing Agreement is a writing, the contents of which speak for themselves.

- 84. Deny each and every averment contained in the introductory sentence of paragraph 84.
- (a) Admit that Hemispherx entered in agreement with Rodman & Renshaw, LLC on May 8, 2008, and that the Company entered into Securities Purchase Agreements with two institutional investors on May 10, 2009; and further aver that the May 8, 2009 agreement and the Securities Purchase Agreements are writings, the contents and terms of which speak for themselves.
- (b) Admit that Hemispherx entered into Securities Purchase

  Agreements on May 18, 2009 with two institutional investors; and further aver that the Securities

  Purchase Agreements are writings, the contents and terms of which of which speak for themselves.
- (c) Deny each and every averment of paragraph 84(c); except admit that, pursuant to the May 8, 2009 and May 18, 2009 Securities Purchase Agreements,

  Hemispherx sold shares of stock and warrants to two institutional investors for approximately \$33,712,000 in the aggregate; and further aver that the May 8, 2009 and May 18, 2009 Securities Purchase Agreements are writings, the contents and terms of which speak for themselves.
- (d) Deny each and every averment of paragraph 84(d); except admit that, on July 2, 2008, Hemispherx entered into a \$30 million Common Stock Purchase Agreement ("Purchase Agreement") and registration rights agreement with Fusion Capital Fund II, LLC, that the registration statement was declared effective by the SEC on August 12, 2008, and that, as of September 1, 2009, Hemispherx had sold to Fusion Capital the maximum number of shares that were registered under the Registration Statement, for \$28,111,695; and further aver

that the Purchase Agreement and the Registration Statement are writings, the contents and terms of which speak for themselves.

- 85. Deny each and every averment of paragraph 85 of the Complaint; except admit that paragraph 85 contains a partial excerpt from an investor conference call hosted by Hemispherx on July 22, 2009; and further aver that the July 22, 2009 conference call was transcribed and that the transcript is a publicly available writing, the contents of which speak for themselves.
- 86. Deny each and every averment of paragraph 86 of the Complaint; except are without knowledge or information sufficient to form a belief as to the truth of the paragraph's averments regarding the alleged existence and identity of a purported former Hemispherx employee or whether this alleged person actually made the statements attributed to him or her and said averments are therefore deemed denied.
- 87. Deny each and every averment of paragraph 87 of the Complaint; except admit that this paragraph contains a partial excerpt, with ellipsis and emphasis supplied by Lead Plaintiff, from Hemisherx's Form 10-Q for the quarter ended September 30, 2009, filed with the SEC on November 9, 2009; and further aver that said SEC filing is a writing, the contents of which speak for themselves.
- 88. Deny each and every averment of paragraph 88 of the Complaint; except admit that this paragraph contains a partial excerpt, with emphasis supplied by Lead Plaintiff, from an investor conference call hosted by Hemispherx on December 3, 2009; further aver that the December 3, 2009 conference call was transcribed and that the transcript is a publicly available writing, the contents of which speak for themselves; and expressly deny Lead Plaintiff's mischaracterizations and false representations of the contents of this writing.

- 89. Deny each and every averment of paragraph 89 of the Complaint.
- 90. Deny each and every averment of paragraph 90 of the Complaint; except admit that paragraph 90 contains partial excerpts of an investor conference call hosted by Hemispherx on April 9, 2008; further aver that the April 9, 2008 conference call was transcribed and that the transcript is a publicly available writing, the contents of which speak for themselves; and expressly deny Lead Plaintiff's mischaracterizations and false representations of the contents of this writing.
- 91. Deny each and every averment of paragraph 91 of the Complaint; except admit that this paragraph purports to summarize statements made during an investor conference call hosted by Hemispherx on December 3, 2009; further aver that the December 3, 2009 conference call was transcribed and that the transcript is a publicly available writing, the contents of which speak for themselves; and expressly deny Lead Plaintiff's mischaracterizations and false representations of the contents of this writing.
  - 92. Deny each and every averment of paragraph 92 of the Complaint.
- 93. Deny each and every averment of paragraph 93 of the Complaint; except admit that Hemispherx requested that the FDA waive certain requirements for carcinogenicity studies, that the FDA denied this request, and that paragraph 93 purports to summarize and contains a partial excerpt, with emphasis supplied by Lead Plaintiff, from an article published on November 3, 2009 on *TheStreet.com*; further aver that said article is a writing, the contents of which speak for themselves; and expressly deny the false statements and misrepresentations contained in that article.
- 94. Deny each and every averment of paragraph 94 of the Complaint; except admit that Hemispherx common stock closed at \$1.93 per share on May 3, 2009.

- 95. Deny each and every averment of paragraph 95 of the Complaint; except admit that Hemispherx requested that the FDA waive certain requirements for carcinogenicity studies.
- 96. Deny each and every averment of paragraph 96 of the Complaint; except admit that Hemispherx's reports of its financial condition are true and accurate and set forth in the Company's SEC filings and other publicly available documents, the contents of which speak for themselves; and further admit that paragraph 96 contains a partial excerpt, with ellipsis supplied by Lead Plaintiff, from an investor conference call hosted by Hemispherx on December 3, 2009; and further aver that the December 3, 2009 conference call was transcribed and that the transcript is a publicly available writing, the contents of which speak for themselves.
  - 97. Deny each and every averment of paragraph 97 of the Complaint.
- 98. Deny each and every averment of paragraph 98 of the Complaint; except admit that this paragraph contains a partial excerpt, with ellipses supplied by Lead Plaintiff, from an investor conference call hosted by Hemispherx on December 19, 2007; and further aver that the December 19, 2007 conference call was transcribed and that the transcript is a publicly available writing, the contents of which speak for themselves.
- 99. Deny each and every averment of paragraph 99 of the Complaint; except admit that this paragraph contains partial excerpts of an investor conference call hosted by Hemispherx on April 9, 2008, discussing the status of the Ampligen<sup>®</sup> NDA; and further aver that the April 9, 2008 conference call was transcribed and that the transcript is a publicly available writing, the contents of which speak for themselves.
- 100. Deny each and every averment of paragraph 100 of the Complaint; except admit that this paragraph purports to summarize and contains a partial excerpt, with ellipses

supplied by Lead Plaintiff, from an investor conference call hosted by Hemispherx on July 17, 2008 and further aver that the July 17, 2008 conference call was transcribed and that the transcript is a publicly available writing, the contents of which speak for themselves.

- 101. Deny each and every averment of paragraph 101 of the Complaint; except admit that this paragraph contains partial excerpts of an investor conference call hosted by Hemispherx on July 17, 2008; and further aver that the July 17, 2008 conference call was transcribed and that the transcript is a publicly available writing, the contents of which speak for themselves.
- admit that this paragraph purports to summarize and contains partial excerpts of an investor conference call hosted by Hemispherx on March 19, 2009; and further aver that the March 19, 2009 conference call was transcribed and that the transcript is a publicly available writing, the contents of which speak for themselves; and expressly deny Lead Plaintiff's mischaracterizations and false representations of the contents of this writing.
- 103. Deny each and every averment of paragraph 103 of the Complaint; except admit that Dr. Strayer serves as Hemispherx's medical director and has discussed the status of the clinical development of Ampligen<sup>®</sup> during certain scientific conferences and on certain investor conference calls.
- 104. Deny each and every averment of paragraph 104 of the Complaint; except admit that this paragraph purports to summarize and contains a partial excerpt, with emphasis supplied by Lead Plaintiff, from a Form 8-K Hemispherx filed with the SEC on May 27, 2009; and further aver that said SEC filing is a writing, the contents of which speak for themselves.

- 105. Deny each and every averment of paragraph 105 of the Complaint; except admit that this paragraph purports to summarize and contains partial excerpts of a press release issued by Hemispherx on February 11, 2010; and further aver that said press release is a writing, the contents of which speak for themselves.
- 106. Deny each and every averment of paragraph 106 of the Complaint; except admit that this paragraph contains partial excerpts, with ellipses supplied by Lead Plaintiff, from an FDA guidance document, which is a publicly available writing, the contents of which speak for themselves.
- 107. Deny each and every averment of paragraph 107 of the Complaint; except admit that this paragraph contains partial excerpts from an FDA guidance document, which is a publicly available writing, the contents of which speak for themselves.
- 108. Deny each and every averment of paragraph 108 of the Complaint; except admit that this paragraph contains a partial excerpt from FDA regulations, which are publicly available writings, the contents of which speak for themselves.
- 109. Deny each and every averment of paragraph 109 of the Complaint; except admit that this paragraph purports to summarize and contains partial excerpts of FDA regulations which are publicly available writings the contents of which speak for themselves.
  - 110. Deny each and every averment of paragraph 110 of the Complaint.
- 111. Deny each and every averment of paragraph 111 of the Complaint; except admit that this paragraph contains partial excerpts, with ellipses supplied by Lead Plaintiff, from an FDA guidance document, which is a writing, the contents of which speak for themselves.
- 112. Deny each and every averment of paragraph 112 of the Complaint; except are without knowledge or information sufficient to form a belief as to the truth of the averments

regarding alleged statements made by Dr. Carter at an unidentified conference and said averments are therefore deemed denied, and admit that Hemispherx requested that the FDA waive certain requirements for carcinogenicity studies and that the FDA made a public announcement that it had approved Pfizer's drug Lyrica for the treatment of Fibromyalgia, and that Pfizer had agreed to conduct a third, post-approval clinical trial.

- admit that Hemispherx received a Warning Letter from the FDA on October 15, 1998, and admit that paragraph 113 contains partial excerpts, with ellipses and emphasis supplied by Lead Plaintiff, from the October 15, 2008 letter; and further aver that the letter is a writing, the contents of which speak for themselves.
- admit that Hemispherx received a Warning Letter from the FDA on July 7, 2000, and admit that paragraph 114 contains partial excerpts, with ellipses and emphasis supplied by Lead Plaintiff, from the July 7, 2000 letter; and further aver that the letter is a writing, the contents of which speak for themselves.
- 115. Deny each and every averment of paragraph 115 of the Complaint; except admit that the FDA Warning Letters issued on October 15, 1998 and July 7, 2000 were addressed to Dr. Carter.
- admit that the market for Hemispherx's common stock was open, well-developed and efficient, and that Hemispherx requested that the FDA waive certain requirements for carcinogenicity studies.

- 117. The averments of paragraph 117 of the Complaint purport to state a legal conclusion to which no response is required, and therefore are deemed denied. To the extent these averments are deemed to be factual in nature, they are denied; except that defendants admit that Hemispherx common stock closed at \$3.75 per share on June, 4 2009.
- 118. The averments of paragraph 118 of the Complaint purport to state a legal conclusion to which no response is required, and therefore are deemed denied. To the extent these averments are deemed to be factual in nature, they are denied.
- 119. The averments of paragraph 119 of the Complaint purport to state a legal conclusion to which no response is required, and therefore are deemed denied. To the extent these averments are deemed to be factual in nature, they are denied.
- 120. The averments of paragraph 120 of the Complaint purport to state a legal conclusion to which no response is required, and therefore are deemed denied. To the extent these averments are deemed to be factual in nature, they are denied.
- admit that, on November 2, 2009, Hemispherx issued a press release entitled "Hemispherx Biopharma Updates Chronic Fatigue Syndrome (CFS) Treatment and Commercial Application Programs; Targets Completion of All NDA Regulatory Responses and Initiation of Expanded Clinical Collaborations in CFS;" further aver that the November 2, 2009 press release is a writing, the contents of which speak for themselves; and expressly deny Lead Plaintiff's false representations and mischaracterizations of the contents of this writing.
- 122. The averments of paragraph 122 of the Complaint purport to state a legal conclusion to which no response is required, and therefore are deemed denied. To the extent these averments are deemed to be factual in nature, they are denied; except that defendants admit

that Hemispherx common stock closed at \$1.45 per share on October 30, 2009, and at \$1.33 per share on November 2, 2009, and at \$1.13 per share on November 3, 2009.

- 123. Deny each and every averment of paragraph 123 of the Complaint; except are without knowledge or information sufficient to form a belief as to the truth of the averments regarding Lead Plaintiff's purported analysis of various stock indices and said averments are therefore deemed denied; admit that paragraph 123 purports to summarize portions of Hemispherx's 2008 Form 10-K, filed with the SEC on March 16, 2009; and further aver that said SEC filing is a writing, the contents of which speak for themselves.
- 124. The averments of paragraph 124 of the Complaint purport to state a legal conclusion to which no response is required, and therefore are deemed denied. To the extent these averments are deemed to be factual in nature, they are denied; except that defendants admit that on December 1, 2009, Hemispherx issued a press release entitled "Hemispherx Biopharma Receives Complete Response Letter from FDA on Ampligen New Drug Application for Chronic Fatigue Syndrome; Outlines Additional Recommendations;" and further aver that said press release is a writing, the contents of which speak for themselves.
- 125. The averments of paragraph 125 of the Complaint purport to state a legal conclusion to which no response is required, and therefore are deemed denied. To the extent these averments are deemed to be factual in nature, they are denied; except that defendants admit that Hemispherx common stock closed at \$1.20 per share on December 1, 2009, at \$0.71 per share on December 2, 2009, and at \$0.68 per share on December 3, 2009.
- 126. Deny each and every averment of paragraph 126 of the Complaint; except are without knowledge or information sufficient to form a belief as to the truth of the averments regarding Lead Plaintiff's purported analysis of various stock indices and said averments are

therefore deemed denied; admit that paragraph 126 purports to summarize portions of Hemispherx's 2008 Form 10-K, filed with the SEC on March 16, 2009; and further aver that said SEC filing is a writing, the contents of which speak for themselves.

- 127. The averments of paragraph 127 of the Complaint purport to state a legal conclusion to which no response is required, and therefore are deemed denied. To the extent these averments are deemed to be factual in nature, they are denied; except that defendants admit that Hemispherx's common stock closed at \$1.33 per share on November 2, 2009, and at \$1.20 per share on December 1, 2009.
- 128. The averments of paragraph 128 of the Complaint purport to state a legal conclusion to which no response is required, and therefore are deemed denied. To the extent these averments are deemed to be factual in nature, they are denied.
- 129. The averments of paragraph 129 of the Complaint purport to state a legal conclusion to which no response is required, and therefore are deemed denied. To the extent these averments are deemed to be factual in nature, they are denied.
- 130. The averments of paragraph 130 of the Complaint purport to state a legal conclusion to which no response is required, and therefore are deemed denied. To the extent these averments are deemed to be factual in nature, they are denied.
- 131. The averments of paragraph 131 of the Complaint purport to state a legal conclusion to which no response is required, and therefore are deemed denied. To the extent these averments are deemed to be factual in nature, they are denied.
- 132. Deny each and every averment of the introductory sentence of paragraph 132 of the Complaint; except admit that Hemispherx common stock was traded in an efficient market.

- (a) Admit the averments of paragraph 132(a).
- (b) Admit the averments of paragraph 132(b).
- (c) Admit the averments of paragraph 132(c)
- (d) Admit that Hemispherx filed a Form 10-K with the SEC on March 16, 2009, and aver that said SEC filing is a writing, the contents of which speak for themselves.
- (e) Admit that Hemispherx filed a Form 10-Q with the SEC on November 9, 2009; and aver that said SEC filing is a writing, the contents of which speak for themselves.
- (f) Are without knowledge or information sufficient to form a belief as to the truth of the averments set forth in paragraph 132(f), and said averments are therefore deemed denied.
  - (g) Admit the averments of paragraph 132(g).
  - (h) Admit the averments of paragraph 132(h).
- (i) Deny that "numerous" securities analysts followed Hemispherx; and are without knowledge or information sufficient to form a belief as to the truth of the remaining averments of paragraph 132(i), and said averments are therefore deemed denied.
- (j) The averments of paragraph 132(j) purport to state a legal conclusion to which no response is required, and therefore are deemed denied. To the extent these averments are deemed to be factual in nature, they are denied.
- 133. The averments of paragraph 133 of the Complaint purport to state a legal conclusion to which no response is required, and therefore are deemed denied. To the extent these averments are deemed to be factual in nature, they are denied.

- 134. The averments of paragraph 134 of the Complaint purport to state a legal conclusion to which no response is required, and therefore are deemed denied. To the extent these averments are deemed to be factual in nature, they are denied.
- 135. The averments of paragraph 135 of the Complaint purport to state a legal conclusion to which no response is required, and therefore are deemed denied. To the extent these averments are deemed to be factual in nature, they are denied.
- admit that Lead Plaintiff purports to bring this action on behalf of an alleged class of persons who purchased Hemispherx common stock during the Class Period; and further aver that this action is not properly maintainable as a class action because Lead Plaintiff cannot meet the requirements for the maintenance of a class action set forth in Federal Rule of Civil Procedure 23.
- 137. The averments of paragraph 137 of the Complaint purport to state a legal conclusion to which no response is required, and therefore are deemed denied. To the extent these averments are deemed to be factual in nature, they are denied; except admit that Hemispherx's stock common was traded throughout the putative Class Period; are without knowledge or information sufficient to form a belief as to the truth of the averment concerning the number of members of the alleged class; and further aver that this action is not properly maintainable as a class action because Lead Plaintiff cannot meet the requirements for the maintenance of a class action set forth in Federal Rule of Civil Procedure 23.
- 138. The averments of paragraph 138 of the Complaint purport to state a legal conclusion to which no response is required, and therefore are deemed denied. To the extent these averments are deemed to be factual in nature, they are denied; and further aver that this

action is not properly maintainable as a class action because Lead Plaintiff cannot meet the requirements for the maintenance of a class action set forth in Federal Rule of Civil Procedure 23.

- 139. The averments of paragraph 139 of the Complaint purport to state a legal conclusion to which no response is required, and therefore are deemed denied. To the extent these averments are deemed to be factual in nature, they are denied; and further aver that this action is not properly maintainable as a class action because Lead Plaintiff cannot meet the requirements for the maintenance of a class action set forth in Federal Rule of Civil Procedure 23.
- 140. The averments of paragraph 140 of the Complaint purport to state a legal conclusion to which no response is required, and therefore are deemed denied. To the extent these averments are deemed to be factual in nature, they are denied; and further aver that this action is not properly maintainable as a class action because Lead Plaintiff cannot meet the requirements for the maintenance of a class action set forth in Federal Rule of Civil Procedure 23.
- 141. The averments of paragraph 141 of the Complaint purport to state a legal conclusion to which no response is required, and therefore are deemed denied. To the extent these averments are deemed to be factual in nature, they are denied; and further aver that this action is not properly maintainable as a class action because Lead Plaintiff cannot meet the requirements for the maintenance of a class action set forth in Federal Rule of Civil Procedure 23.

#### **COUNT I**

142. Repeat and reallege their responses to the averments of paragraphs 1 through 141 of the Complaint as though fully set forth herein.

- 143. The averments of paragraph 143 of the Complaint purport to state a legal conclusion to which no response is required, and therefore are deemed denied. To the extent these averments are deemed to be factual in nature, they are denied.
- 144. The averments of paragraph 144 of the Complaint purport to state a legal conclusion to which no response is required, and therefore are deemed denied. To the extent these averments are deemed to be factual in nature, they are denied.
- 145. The averments of paragraph 145 of the Complaint purport to state a legal conclusion to which no response is required, and therefore are deemed denied. To the extent these averments are deemed to be factual in nature, they are denied.
- 146. The averments of paragraph 146 of the Complaint purport to state a legal conclusion to which no response is required, and therefore are deemed denied. To the extent these averments are deemed to be factual in nature, they are denied.

## **COUNT II**

- 147. Repeat and reallege their responses to the averments of paragraphs 1 through 146 of the Complaint as though fully set forth herein.
- 148. The averments of paragraph 148 of the Complaint purport to state a legal conclusion to which no response is required, and therefore are deemed denied. To the extent these averments are deemed to be factual in nature, they are denied.

## **SECOND DEFENSE**

The Complaint, including each Count and claim contained therein, fails to state a claim upon which relief can be granted.

### THIRD DEFENSE

The Complaint, including each Count and claim contained therein, is barred, in

whole or in part, because the Complaint fails to comply with the pleading requirements of the Federal Rules of Civil Procedure and the Private Securities Litigation Reform Act of 1995, 15 U.S.C. § 78u-4.

# **FOURTH DEFENSE**

Defendants did not engage in any misconduct sufficient to impose liability under Section 10(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78j(b), or Rule 10b-5, 17 C.F.R. § 240.10b-5, promulgated thereunder by the Securities and Exchange Commission.

# **FIFTH DEFENSE**

Defendants William A. Carter, M.D. and David R. Strayer, M.D. did not engage in any misconduct sufficient to impose liability under Section 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. § 78t(a).

## SIXTH DEFENSE

Because neither Lead Plaintiff nor any member of the putative Class can establish the primary liability necessary to support their claims for "control person" liability under Section 20(a) of the Securities Exchange Act of 1934, such claims are barred.

## **SEVENTH DEFENSE**

Defendants acted in good faith and did not directly or indirectly induce the act or acts constituting the alleged violation(s) or cause(s) of action.

#### **EIGHTH DEFENSE**

Every misrepresentation and omission alleged in the Complaint (none being admitted) was made in good faith conformity with the rules and regulations of the Securities and Exchange Commission and, therefore, pursuant to Section 23(a) of the Securities Exchange Act of 1934, there is no liability for any misrepresentation or omission so alleged.

## NINTH DEFENSE

None of the misrepresentations and omissions alleged in the Complaint was made with the requisite degree of scienter necessary to impose liability under Section 10(b) of the Securities Exchange Act of 1934 or Rule 10b-5 promulgated thereunder.

## TENTH DEFENSE

No conduct of defendants was the proximate cause or cause in fact of any alleged damages to Lead Plaintiff or any member of the putative Class.

# **ELEVENTH DEFENSE**

Lead Plaintiff and the putative Class were expressly advised in the challenged public statements of the material facts and risks to Hemispherx that the Complaint alleges were the cause of Lead Plaintiff's and the putative Class' purported damages.

## TWELFTH DEFENSE

Defendants are not liable because some or all of the matters now claimed by Lead Plaintiff to be the subject of misrepresentations or omissions were publicly disclosed or were in the public domain and, as such, were available to Lead Plaintiff and each member of the putative Class and were at all times reflected in the price of Hemispherx's common stock.

# **THIRTEENTH DEFENSE**

At the time they purchased Hemispherx common stock, Lead Plaintiff and each member of the putative Class had actual or constructive knowledge of some or all of the facts alleged in the Complaint upon which defendants' liability is asserted; therefore, each such plaintiff assumed the risk that the value of Hemispherx common stock could decline.

#### FOURTEENTH DEFENSE

Lead Plaintiff and each member of the putative Class would have acquired

Hemispherx common stock even if they had known, at the time they acquired the stock, of the

allegedly untrue statements of material fact, omissions of material fact, misleading statements or other allegedly wrongful conduct (none being admitted) upon which defendants' purported liability rests.

# FIFTEENTH DEFENSE

When they acquired shares of Hemispherx common stock, Lead Plaintiff and each member of the putative Class knew, or in the exercise of reasonable care should have known, of the facts allegedly misrepresented or omitted by defendants; each such plaintiff was negligent and this negligence was a cause-in-fact and a proximate cause of any alleged damages.

Therefore, such negligence bars recovery in whole or in part by each such plaintiff.

# **SIXTEENTH DEFENSE**

Any depreciation in the market price of the securities purchased by Lead Plaintiff and members of the putative Class resulted from factors other than defendants' alleged misrepresentations or omissions.

# **SEVENTEENTH DEFENSE**

The Complaint, including each Count and claim contained therein, is barred in whole or in part because, to the extent Lead Plaintiff or members of the putative Class have suffered any damages, they have failed to mitigate those damages.

## **EIGHTEENTH DEFENSE**

Any damages recovery by Lead Plaintiff or a member of the putative Class is subject to an offset for the amount of tax benefits actually received by that plaintiff through its investments.

# **NINETEENTH DEFENSE**

Certain of the alleged untrue statements of material fact, misleading statements or

other challenged statements made by defendants are rendered non-actionable by the Safe Harbor provisions of the Private Securities Litigation Reform Act of 1995, as codified at 15 U.S.C. § 78u-5.

## TWENTIETH DEFENSE

None of the misrepresentations and omissions alleged in the Complaint has directly or indirectly caused any injury to Lead Plaintiff or any member of the putative Class.

## TWENTY-FIRST DEFENSE

If there were any misrepresentations or omissions in defendants' public statements as alleged (which allegations are specifically denied), Lead Plaintiff and each member of the putative Class did not reasonably rely on such alleged misrepresentation or omission, or on any alleged superior expertise and knowledge of defendants, or on the integrity of the market, in purchasing or acquiring Hemispherx common stock.

# **TWENTY-SECOND DEFENSE**

If there were any misrepresentations or omissions in defendants' statements as alleged (which allegations are specifically denied), such alleged misrepresentations or omissions were not material within the meaning of any applicable statute, regulation, common law or otherwise.

## TWENTY-THIRD DEFENSE

Any alleged drop in Hemispherx's stock price was not caused by any material misrepresentation or omission allegedly made by defendants.

# **TWENTY-FOURTH DEFENSE**

The claims asserted in the Complaint are barred in whole or in part by the doctrines of waiver, estoppel, ratification, unclean hands and/or other related doctrines and principles.

## TWENTY-FIFTH DEFENSE

The Complaint and each Count and claim contained alleged therein are barred, in whole or in part, because any damages incurred by Lead Plaintiff or a member of the putative Class were sustained as a direct and proximate result of intervening and superseding acts and/or omissions of persons or entities, other than defendants, that were outside the control of defendants, and/or by intervening and superseding events that were beyond the control of, and could not have been foreseen by, defendants.

# TWENTY-SIXTH DEFENSE

The alleged damages of Lead Plaintiff and members of the putative Class are speculative and, therefore, not recoverable.

# **TWENTY-SEVENTH DEFENSE**

The Complaint, including each Count and claim contained therein, is barred in whole or in part because any alleged damages to Lead Plaintiff or a member of the putative Class were caused by that plaintiff's own negligence in failing to conduct a reasonably diligent investigation of the risks associated with its investment.

## TWENTY-EIGHTH DEFENSE

The Complaint, including each Count and claim contained therein, is barred because Lead Plaintiff and the putative Class knew that investing in Hemispherx involved a high degree of risk and voluntarily assumed such risk.

#### TWENTY-NINTH DEFENSE

Neither Lead Plaintiff nor any other member of the putative Class can meet the requirements of Federal Rule of Civil Procedure 23, and, therefore, this action is not properly maintainable as a class action.

# **THIRTIETH DEFENSE**

The Complaint fails to plead against defendants with the specificity required by the Federal Rules of Civil Procedure and the Private Securities Litigation Reform Act of 1995.

This lack of specificity makes it impossible for defendants to determine at this time which additional defenses they may have; therefore, defendants reserve the right to assert all applicable defenses once the precise nature of the relevant circumstances or events is determined through discovery.

# THIRTY-FIRST DEFENSE

Defendants reserve the right to amend the above answer and affirmative defenses consistent with further discovery and evidence throughout the pendency of this action.

WHEREFORE, defendants demand that judgment be entered in their favor and against Lead Plaintiff and all members of the putative Class on each and every count of the Complaint; and also demand that defendants be awarded their costs and attorneys' fees and such other relief as the Court deems just and proper.

/s/ Robert L. Hickok

Robert L. Hickok Gay Parks Rainville Michele C. Zarychta Thomas T. Watkinson, II William A. Liess Joseph W. Jesiolowski PEPPER HAMILTON LLP 3000 Two Logan Square Eighteenth & Arch Streets Philadelphia, PA 19103 (215) 981-4000

Attorneys for Defendants Hemispherx Biopharma, Inc. William A. Carter, M.D. David R. Strayer, M.D.

Dated: May 14, 2010

# **CERTIFICATE OF SERVICE**

I, Gay Parks Rainville, hereby certify that on May 14, 2010 I caused a true and correct copy of Defendants' Answer And Defenses Of Defendants To Consolidated [Amended] Class Action Complaint to be served upon the following Co-Lead Counsel for Lead Plaintiff via ECF and by electronic and regular mail:

Sherrie R. Savett Carole A. Broderick Barbara A. Podell Eric Lechtzin BERGER & MONTAGUE, P.C. 1622 Locust Street Philadelphia, PA 19103

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/s/Gay Parks Rainville